AUG 3 1 2011

510(k) Summary

Submitter:	Hsue-mei Lee Manager of Quality Assurance Department Apex BioTechnology Corp. No. 7, Li-Hsin Road V, Hsinchu Science Park Hsinchu, 30078 CHINA (TAIWAN) email: hsue-mei@apexbio.com Phone: 011-886-3-5641952 FAX: 011-886-3-5678302
Contact Person:	Hsue-mei Lee Manager of Quality Assurance Department Apex BioTechnology Corp. No. 7, Li-Hsin Road V, Hsinchu Science Park Hsinchu, 30078 CHINA (TAIWAN) email: hsue-mei@apexbio.com Phone: 011-886-3-5641952 FAX: 011-886-3-5678302
Date Prepared:	August 18, 2011
Trade Names:	MEG-2 Blood Glucose Monitoring System, MEG-2 Blood Glucose Test Strips, MEG-2 Glucose Control Solutions, MEG-2 Multi Blood Glucose Monitoring System, MEG-2 Multi Blood Glucose Test Strips
Classification:	Glucose test system, 21 CFR 862.1345, Class II Single (Specified) Analyte Controls (Assayed And Unassayed), 21 CFR 862.1660, Class I, reserved
Product Codes:	CGA, NBW, JJX
Predicate Devices:	GlucoSure STAR meter and test strips Contrex Plus glucose control solutions
Device Description:	The MEG-2 blood glucose monitoring system consists of a meter, test strips and three levels of control solution. It is used for testing of blood glucose by self-testers at home. The MEG-2 Multi blood glucose monitoring system consists of a meter, test strips and three levels of control solution. It is used for testing of blood glucose by professional testers in healthcare facilities.

Intended Use:	MEG-2 Blood Glucose Monitoring System: The MEG-2 Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Testing is done outside the body (In Vitro diagnostic use). It is indicated for lay use by people with diabetes, as an aid to monitoring levels in Diabetes Mellitus and should only be used by a single patient. This system should not be shared. It is not indicated for the diagnosis or screening of diabetes or for neonatal use. Alternative site testing can be used only during steady-state blood glucose conditions. MEG-2 Blood Glucose Test Strips: The MEG-2 Blood Glucose Test Strips are to be used with the MEG-2 Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm. It is for use outside of the body (in vitro diagnostic use). The MEG-2 Blood Glucose Monitoring Systems are plasma-calibrated for easy comparison to lab results. They are intended for lay use by people with diabetes and should only be used by a single patient. This system should not be shared. They are not indicated for the diagnosis or screenng of diabetes or for neonatal use. MEG-2 Glucose Control Solution: The MEG-2 Glucose Control Solutions are used with the MEG-2 and MEG-2 Multi Blood Glucose Monitoring Systems to indicate appropriate user technique and to indicate that the test strip and meter are functioning properly.. MEG-2 Multi Blood Glucose Monitoring System: The MEG-2 Multi Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Testing is done outside the body (In Vitro diagnostic use). It is indicated to be use for multiple patients in a clinical setting by healthcare professionals, as an aid to monitoring levels in Diabetes Mellitus. This system is only used with single-use, auto-disabling lancing device. It is not indicated for the diagnosis or screening of diabetes or for neonatal use. Alternative site testing can be used only during steady-state blood glucose conditions. MEG-2 Multi Blood Glucose Test Strips: The MEG-2 Multi Blood Glucose Test Strips are to be used with the MEG-2 Multi Blood Glucose Meter; it measures glucose in capillary whole blood taken from a fingertip, palm, or forearm. It is for use outside of the body (in vitro diagnostic use). It is indicated in a clinical setting to be used for multiple patients by healthcare professionals. This system is only used with single-use, auto-disabling lancing device.

Comparison of Technological Characteristics:	The MEG-2 meter uses the same test algorithm as the predicate. The meter has been modified from a 4-button system to a 3-button one with a new battery type. The test strip and test strip holder have been modified to allow automatic detection of the calibration code upon insertion of the test strip. The core functionality of the predicate meter has been retained in the MEG-2 meter. The MEG-2 Multi meter and MEG-2 Multi test strips are identical to their MEG-2 counterparts except for labeling to distinguish that they are for professional use (MEG-2 Multi) and home use (MEG-2), respectively. The MEG-2 control solutions have the same formula as the predicate with the addition of a red dye and slight adjustment of the glucose values for each level of control solution.
Non-Clinical Testing:	Testing was conducted as follows: Software verification and validation plus software integration testing, Battery Life verification, Test Strip Holder Life verification, Control Solution Qualification, Control solution real-time and use-life stability testing, Drop testing, EMC and Electrical Safety testing, Linearity testing, Precision testing, Hematocrit range testing, Interference testing, test strip stability testing, test strip open bottle use life testing, and testing of the test strip autocode manufacturing and quality control processes. Results demonstrate substantial equivalence to the predicate devices.
Clinical Testing	An Accuracy and User Performance Evaluation study was conducted with 141 test subjects. Blood testing was done by healthcare professionals and non-professional self-testers against the YSI reference instrument. Control solution testing was also conducted. Results demonstrate substantial equivalence to the predicate device.
Conclusion:	Clinical and non-clinical testing demonstrated that the MEG-2 and MEG-2 Multi systems (meters, test strips and control solutions) perform in a substantially equivalent manner to that of the predicate. We conclude that the MEG-2 and MEG-2 Multi meters, test strips and control solutions are substantially equivalent to their predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

AUG 3 1 2011

Apex BioTechnology Corporation
c/o Hsue-mei Lee
Manager of Quality Assurance Department
No. 7 Li-Hsin Road V, Hsinchu Science Park
Hsinchu, China (Taiwan) 30078

Re: k101204
Trade Name: MEG-2 Blood Glucose Monitoring System,
MEG-2 Multi Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, CGA, JJX
Dated: August 19, 2011
Received: August 22, 2011

Dear Hsue-mei Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indications for Use Statement

510(k) Number (if known): k101204

Device Name: MEG-2 Blood Glucose Monitoring System

Indications for Use:

MEG-2 Blood Glucose Monitoring System:

The MEG-2 Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Testing is done outside the body (In Vitro diagnostic use). It is indicated for lay use by people with diabetes, as an aid to monitoring levels in Diabetes Mellitus and should only be used by a single patient. This system should not be shared. It is not indicated for the diagnosis or screening of diabetes or for neonatal use. Alternative site testing can be used only during steady-state blood glucose conditions.

MEG-2 Blood Glucose Test Strips:

The MEG-2 Blood Glucose Test Strips are to be used with the MEG-2 Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm. It is for use outside of the body (in vitro diagnostic use). They are intended for lay use by people with diabetes and should only be used by a single patient. This system should not be shared. They are not indicated for the diagnosis or screenng of diabetes or for neonatal use.

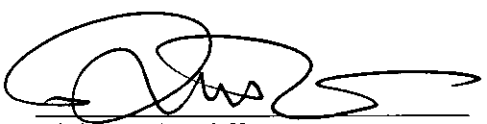
MEG-2 Glucose Control Solution:

The MEG-2 Glucose Control Solutions are used with the MEG-2 and MEG-2 Multi Blood Glucose Monitoring Systems to indicate appropriate user technique and to indicate that the test strip and meter are functioning properly.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k): k101204

Page 1 of 1

1 of 2

Indications for Use Statement

510(k) Number (if known): k101204

Device Name: MEG-2 Multi Blood Glucose Monitoring System

MEG-2 Multi Blood Glucose Monitoring System:

The MEG-2 Multi Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Testing is done outside the body (In Vitro diagnostic use). It is indicated to be use for multiple patients in a clinical setting by healthcare professionals, as an aid to monitoring levels in Diabetes Mellitus. This system is only used with single-use, auto-disabling lancing device. It is not indicated for the diagnosis or screening of diabetes or for neonatal use. Alternative site testing can be used only during steady-state blood glucose conditions.

MEG-2 Multi Blood Glucose Test Strips:

The MEG-2 Multi Blood Glucose Test Strips are to be used with the MEG-2 Multi Blood Glucose Meter; it measures glucose in capillary whole blood taken from a fingertip, palm, or forearm. It is for use outside of the body (in vitro diagnostic use). It is indicated in a clinical setting to be used for multiple patients by healthcare professionals. This system is only used with single-use, auto-disabling lancing device.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k): k101204

Page 1 of 1

2 of 2